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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,843	11/24/2003	David A. Schwartz	SOL.003.DIV1	5194

26990	7590	10/16/2007
DAVID B. WALLER & ASSOCIATES		
5677 OBERLIN DRIVE		
SUITE 214		
SAN DIEGO, CA 92121		

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,843	Applicant(s) SCHWARTZ, DAVID A.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7,35,38,49 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7,35,38,49 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2007 has been entered.

2. The replacement drawings filed March 28, 2007, were accepted by the examiner in the Office action mailed May 22, 2007. See the Office Action Summary, PTOL-326, item 10, included with that action. The replacement drawings filed August 31, 2007, being identical to those previously submitted on March 28, 2007, are also accepted by the examiner.

3. The substitute specification filed August 31, 2007 has not been entered because the marked-up copy of the substitute specification is not identical to the clean copy of the substitute specification in at least one location. Note page 4, line 30, of the marked-up copy of the substitute specification (i.e., "N(COR¹⁵) N(R¹⁵),") and page 3, line 19, of the clean copy of the substitute specification (i.e., "N(R¹⁵), N(COR¹⁵),"). The examiner has not reviewed the marked-up copy and the clean copy of the substitute specification for other discrepancies, this being Applicant's responsibility. The presence of any differences between the marked-up copy and the clean copy of the substitute specification undermines the very reason why 37 CFR 1.125(c) requires the submission of the marked-up copy of the substitute specification, i.e. so that the examiner can determine what changes to the specification are being proposed by Applicant.

In addition, numerous changes to Example 10 are proposed in the substitute specification, e.g., concerning the reactants, reactant concentrations, and molar extinction coefficient.

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Applicant does not appear to have stated where these changes to the specification are supported by the original disclosure of the invention and why they do not constitute new matter.

4. The claim listing filed August 31, 2007 is not in compliance with 37 CFR 1.121(c)(1). This rule requires that the sheets which contain the text of any part of the claims can not contain any other part of the amendment. However, in Applicant's claim listing, the first paragraph at the top page is a paragraph concerning the substitute specification.

The amendments to claims 5-7, 35, and 38 contained in the response filed August 31, 2007, are in improper format under 37 CFR 1.121(c)(2) because they contain and repeat amendment markings from the amendments made to the claims in the paper filed April 16, 2007. The amendment to claim 35, section (ii) contained in the response filed August 31, 2007 is in improper format under 37 CFR 1.121(c)(2) because "amino or one" has been re-inserted into the claim without underlining, and because "biomolecule" has been changed to "biological molecule" without showing "biomolecule" with strike-through. The amendment to claim 52 is in improper format under 37 CFR 1.121(c) because of the use of an incorrect status identifier. A claim with amendment markings can not be given status identifier "(Original)". In addition, the amendment to claim 52 is not in compliance with 37 CFR 1.121(c)(2) because it shows a struck-through "a-bromoacetamide", which word was not present in the previous version of the claim. The amendment format of any future amendments to the claims should be carefully checked to ensure compliance with the rules. Amendments after final rejection which are found not to be in compliance with 37 CFR 1.121 will not be entered.

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5. The disclosure is objected to because of the following informalities: At page 4, line 27, "limited" is misspelled. At page 51, line 30, a SEQ ID NO needs to be inserted after the nucleotide sequence. See 37 CFR 1.821(d). Appropriate correction is required.

6. Claims 5, 6, 35, 38, 49, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a derivative thereof" at claim 5, line 3; claim 35, line 6; and claim 38, line 7; is indefinite because it is not clear what degree of structural and/or functional similarity is required to be present in a compound of formula II or Va and a second compound in order for the second compound to be considered a "derivative" of the compounds of formulas II or Va. For example, it is not clear if a derivative must still comprise a hydrazine group and/or an aliphatic divalent group. While Applicant's specification at page 9, line 26 - page 10, line 24, describes examples of derivatives (note Applicant's use of the word "includes" at page 9, line 26), an example is not a definition. The word "derivative" also does not have any art-accepted definition.

7. Claims 6 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claim 6 recites that R can be a saturated or unsaturated carbocyclic moiety of 3 to 20 atoms. However, with respect to cyclic groups, the independent claim limits R to being an aliphatic divalent cycloalkene group. Accordingly, dependent claim 6 is at least in part broader in scope than the independent claim and is therefore an improper dependent claim. Independent claim 5 recites R¹ and R² groups which are saturated

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straight chains of 3 to 20 carbon atoms. However, in the formula recited in dependent claim 7, the two groups which correspond to R^1 and R^2 of the independent claim are methyl groups, and are not encompassed by the independent claim.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 5-7, 35, 38, 49, and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the WO Patent Application 01/70685. See, e.g., claims 5-7, 32, 35, and 38 of the WO Patent Application '685. The WO Patent Application '685 is available as prior art against the instant claims because of the current lack of an acceptable claim for priority under 35 U.S.C. 120.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 93/14779. The WO Patent Application '779 teaches a compound at page 22, Example 5. In Example 6, the compound of Example 5 of the WO Patent Application '779 is reacted with an arginine derivative, which is a synthetic biological molecule, and the product is then conjugated to the amino group of a solid phase resin (which corresponds to Applicant's surface) in Example 7. The reaction product of the compound of Example 5 and the arginine derivative of the WO Patent Application '779 is deemed to be a derivative of Applicant's compound of formula II in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of the WO Patent Application '779 and Applicant's claimed compounds to shift the

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burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of the WO Patent Application '779.

11. Claims 5 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Whelihan (U.S. Patent No. 6,238,860). Whelihan teaches polypeptides which are synthesized with a Glu-Gly-Gly-Gly-Ser spacer sequence, modified with a hydrazide functionality, and then immobilized on an aldehyde-functional methacrylate resin support (which corresponds to Applicants' surface). See column 14, lines 12-52. The polypeptide-spacer-hydrazide reaction product of Whelihan is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Whelihan and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of Whelihan.

12. Claims 5 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sivam et al (U.S. Patent No. 5,521,290). Sivam et al '290 teaches derivatizing a monoclonal antibody with sulfhydryl groups, reacting a hydrazide-containing bifunctional linker of formula I with the derivatized monoclonal antibody, and then reacting the monoclonal antibody hydrazide with ricin A which has been oxidized to form aldehyde groups on its oligosaccharide moieties (and which corresponds to Applicants' natural or synthetic biological molecule of claim 38, step (ii)). See column 5, lines 60-67, and column 18, lines 25-61. The reaction product of the derivatized monoclonal antibody and the bifunctional linker of Sivam et al '290 is deemed to be a derivative

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of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Sivam et al '290 and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of Sivam et al '290.

13. Applicant's arguments filed August 31, 2007 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, second paragraph, based upon Applicant's use of the term "derivative" is maintained. The examiner disagrees with Applicant as to whether or not claims are to be interpreted narrowly. MPEP 2111, first paragraph, states that "During patent examination, the claims must be given their broadest reasonable interpretation consistent with the specification." (The examiner has no opinion as to how claims are to be interpreted with respect to the Doctrine of Equivalence [sic - Equivalents], this being outside the scope of the examiner's competence.) Applicant has not chosen to be his/her own lexicographer with respect to the term "derivative", because no definition of the term has been provided in the specification. As noted by the examiner in the rejection, Applicant's specification at page 9, line 26 through page 10, line 24, only provides examples of derivatives, and does not provide a definition of the term. An example does not constitute a definition. Applicant's arguments suggest that the word "includes" has been removed in each place it occurred in this "definition". However, a quick review of the proposed substitute specification filed August 31, 2007 (see, e.g., page 12, line 24, of the marked-up copy) shows that this is not true. Given the amendment format chosen by

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Applicant for the proposed substitute specification (strikethrough of an entire page-long paragraph and underlining of an entire page-long replacement paragraph), it is impossible, absent a word-by-word comparison of the two paragraphs, to determine whether any or all other occurrences of “includes” have been changed.

The objection to claims 6 and 7 under 37 CFR 1.75(c) is maintained. Applicant did not make any amendments to the claims in order to address the objections; rather, Applicant merely repeated previously submitted amendments.

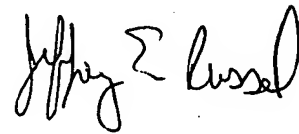
The rejection over the WO Patent Application 01/70685 is maintained in the absence of an acceptable claim for priority.

The anticipation rejection of claim 5 over the WO Patent Application 93/14779 is maintained. The examiner does not assert that the reference teaches a compound satisfying the requirements of formula II. However, claim 5 is not limited to compounds of formula II, but instead, as an alternative, also embraces derivatives of compounds of formula II. The term “includes” occurs in the specification’s discussion of the term “derivative”, both in the specification as originally filed and in the proposed substitute specification filed August 31, 2007. There is no definition of “derivative” in either the specification as originally filed or the proposed substitute specification. Each specification merely lists examples of derivatives, and examples do not constitute definitions. The anticipation rejections over Whelihan (U.S. Patent No. 6,238,860) and over Sivam et al (U.S. Patent No. 5,521,290) are maintained for analogous reasons.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and a cursive "Russel".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

October 3, 2007